

NON-CONFIDENTIAL 04-1323, -1487

United States Court of Appeals For the Federal Circuit

ARTHROCARE CORPORATIÓN,

Plaintiff/Counterclaim Defendant-Appellee,

and

ETHICON, INC.,

Counterclaim Defendant-Appellee,

ν

SMITH & NEPHEW, INC.,

Defendant/Counterclaimant-Appellant.

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE IN 01-CV-504, CHIEF JUDGE SUE L. ROBINSON

REPLY BRIEF FOR DEFENDANT/COUNTERCLAIMANT-APPELLANT SMITH & NEPHEW, INC.

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CERTIFICATE OF INTEREST

Counsel for the Defendant/Counterclaimant-Appellant Smith & Nephew, Inc., certify the following:

1. The full name of every party represented by us is:

Smith & Nephew, Inc.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by us is:

See above

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party represented by us are:

Smith & Nephew Holdings, Inc.
Smith & Nephew (Overseas) Limited
TP Limited
Smith & Nephew plc

4. The names of all law firms and the partners or associates that appeared for the party now represented by us in the trial court or are expected to appear in this court are:

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MATERIAL OMITTED FROM NON-CONFIDENTIAL BRIEF

The material omitted from the Non-Confidential Brief relates to confidential agreements executed by ArthroCare Corporation and Ethicon, Inc., documents filed under seal with the district court, and Smith & Nephew, Inc.'s counterclaim, the dissemination of which the district court has restricted.

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ARGUMENT

I. Smith & Nephew Preserved its Validity Challenge

Smith & Nephew preserved its Rule 50 rights. It moved for judgment as a matter of law three times. [A73 (citing A15441 (1161:22-1162:2), A15585 (1549:2-5), A15647 (1700:16-23))] The district court prevented the parties from presenting detailed arguments on the motions, informing them that "[a]ll such motions are reserved." [A15585 (1549: 2-5); A15647 ("All your rights are reserved and my decisions are reserved as well.") (emphasis added)); A15586 (1553:7-9)]

Acknowledging that it curtailed further discussions, the court ruled that Smith & Nephew's Rule 50(b) rights were preserved. [A73-74]; see also Wilson Sporting Goods Co. v. David Geoffrey & Assocs., 904 F.2d 677, 683 (Fed. Cir. 1990) (cursory Rule 50 motion not fatal where "the court cut short counsel's statement, making clear its view that . . . it wanted to move on"), overruled in part on other grounds by Cardinal Chem. Co. v. Morton Int'l, Inc., 508 U.S. 83 (1993). Smith & Nephew did not "ignore Rule 50," as ArthroCare contends. Given the court's assurances that all its rights were preserved, Smith & Nephew simply complied with the instructions to move on.

ArthroCare has not shown prejudice or that the spirit of the rule has been offended. <u>Duro-Last, Inc. v. Custom Seal, Inc.</u>, 321 F.3d 1098, 1106 (Fed. Cir.

2003) ("A liberal reading of the [Rule 50] may be appropriate . . . when the failure [to make a detailed motion] is largely a technical one, and no prejudice results."). Rule 50(a) seeks to avoid "surprises and tactical victories at the expense of substantive interests," and to afford the other party an opportunity to cure possible technical defects in its proof. Acosta v. Honda Motor, Co., 717 F.2d 828, 831-32 (3d Cir. 1983).

ArthroCare was fully aware of Smith & Nephew's invalidity challenges.

[A5098-110; A12755-60; A15498-502 (1292-1305)] It made a deliberate decision not to put on any rebuttal invalidity evidence, opting only to cross-examine Smith & Nephew's invalidity expert. ArthroCare has not shown any prejudice or even argued that it would have proceeded differently had the court allowed Smith & Nephew to present a more detailed Rule 50(a) motion.

II. No Reasonable Jury Could Have Found the '536 Patent Not Invalid

ArthroCare contests the anticipation evidence on only two limitations: "connector" and "electrically conducting fluid." ACB at 17-32. As a preliminary matter, Smith & Nephew must clarify a misleading impression created by ArthroCare's brief. ArthroCare emphasizes that an examiner found the '536 patent's claims patentable over the Roos references during a reexamination. ACB

ArthroCare mistakenly argues this finding is substantial evidence supporting the verdict. ACB at 12 & 18. Although a patent's issuance creates a presumption of validity, it alone is never substantial evidence of validity. See Verdegaal Bros.

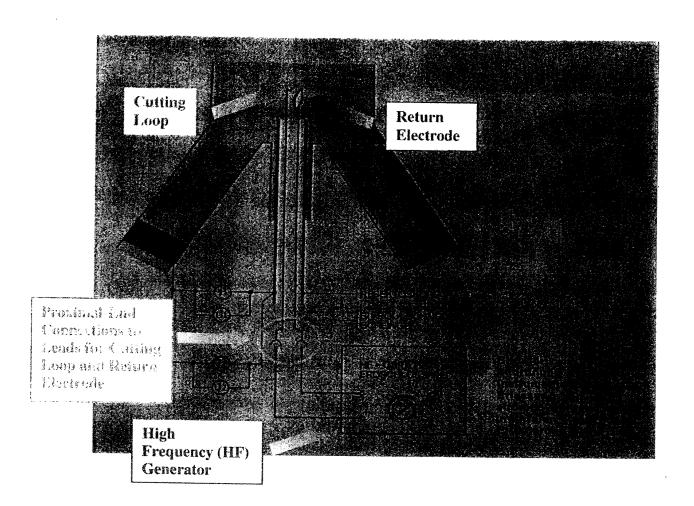
at 9, 12, 18 & 23. ArthroCare omits, however, that three months later the PTO reinstituted reexamination, [A18215-21], and recently rejected the '536 patent, expressly finding that the Roos references disclose the "connector" and "electrically conducting fluid" limitations, [A26892-94; A26897].

A. Connector

The asserted '536 claims recite a "connector near the proximal end of the shaft electrically coupling the electrode terminal to the electrosurgical power supply." [A399 (18:19-21)] The court construed "connector" to mean "structure that electrically links the electrode terminal to the high frequency power supply." [A17; A15652 (1718:1-8)]

Even if the jury was free to discount the testimony of Smith & Nephew's expert, ACB at 31-32, it was not free to disregard the plain disclosure of the Roos article itself, [A18719-24; A18724.1-724.6]. The Roos article discloses a probe with active and return electrodes at the distal end that are "connect[ed]" to "a high-frequency generator" located outside the patient's body. [A18728; A18720 (Fig. 1)] As shown in Figure 8, the electrodes connect to wires that run toward the

Inc. v. Union Oil Co., 814 F.2d 628 (Fed. Cir. 1987) (reversing a validity verdict for lack of substantial evidence). ArthroCare's assertion that invalidity proof is heightened here, ACB at 12, 18 & 23, is incorrect. See Superior Fireplace Co. v. Majestic Prods. Co., 270 F.3d 1358, 1367 (Fed. Cir. 2001) (invalidity standard is the same for originally and reexam issued patents); Am. Hoist & Derrick Co. v. Sowa & Sons, 725 F.2d 1350, 1360 (Fed. Cir. 1984) (The "burden [of proving invalidity] never changes and is to convince the court of invalidity by clear evidence.").



proximal end of the probe. [A18723; see also A18675 (Fig. 8)] The only connector shown in Figure 9 is located at the probe's proximal end. [A18723] Because the electrical wires do not exit along the probe's length, they must run to the connector shown in Figure 9. Further, Figure 10 (see facing page) explicitly shows the proximal-end electrical connections between the high frequency generator and the electrode wires. [A18724; A18729-30]

Even if the multi-function connector of Figure 9 provides structure that connects the fluid supply or optical system to the probe, see ACB at 31, this does not preclude it from also providing the electrical connection. This connector is the only structure for coupling the probe to any of the external systems, which indisputably include the generator. [A18720-24 (Figs. 1 & 10)] It is unreasonable for ArthroCare to suggest or for the jury to have found that this proximal-end connector does not link the active electrode to the generator.

The Roos patent also discloses the claimed connector. Its figures and text teach that the generator connects to the electrodes through electrical leads running to the "rear end" (i.e., proximal end) of the probe. [A18671-75 (Abstract, Figs. 4, 6, & 8); A18676-79 (1:5-15, 4:3-4, 5:2-10, 6:67-7:7 (leads form a single cable "leading to the rear end of endoscope 13"), 7:50-53, & 8:49-54)]

In light of this disclosure, ArthroCare's arguments that the Roos references do not disclose the connector's function and location have no factual basis. The

Roos references need not expressly discuss the function or the location of the connector to disclose it sufficiently for anticipation purposes. <u>EMI Group N. Am.</u>, <u>Inc. v. Cypress Semiconductor Corp.</u>, 268 F.3d 1342, 1350 (Fed. Cir. 2001). A reference anticipates if it discloses, either expressly or inherently, all of the claim's limitations. <u>See Schering Corp. v. Geneva Pharms.</u>, Inc., 339 F.3d 1373, 1379 (Fed. Cir. 2003); <u>EMI</u>, 268 F.3d at 1350.

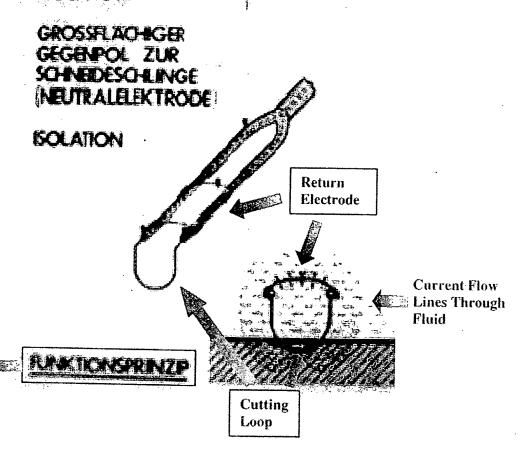
B. Electrically Conducting Fluid

The '536 patent claims recite "electrically conducting fluid" for "generat[ing] a current flow path between the return electrode and the electrode terminal [i.e., the active electrodes]." [A399 (18:26-28)] The court essentially adopted Smith & Nephew's proposed construction in holding that "electrically conducting fluid" means "any fluid that facilitates the passage of electrical current," [A18; A15652 (1719:1-7)]. "Facilitate" means "to make easy or easier." [A26914; see also A26905 (defining "facilitate" as "3. Physiology. Increase the likelihood of, strengthen (a response). . .")] In the context of the '536 patent, the conductive fluid makes the passage of electrical current easier by providing "a

² ArthroCare argued that "electrically conducting fluid" should mean "fluid with a conductivity similar to blood or saline." [A13615 (151-53)] The court rejected this proposal and adopted Smith & Nephew's construction, substituting "facilitates" for "allows." [A18; A8086-87; A3591] Nevertheless, ArthroCare argues that the Roos references do not discloses saline or Ringer's lactate. ACB at 20 & 25. Unquestionably, the failure to disclose a specific type of electrically conducting fluid does not show that these references lack any such fluid.

Bild 6: Bipolere Elektroden Anordnung zu Schneiden bei transureihreier Resektion: Di Strom fließt von der Schneideschlinge direitst der nahen schildförmigen Neutralelektrod

SOLATION



OPERATING PRINCIPLE [A18728] current flow path between the return electrode and the electrode terminal." [A399 (18:26-28); A8280; A8087 ('536 patent inventor testifying that "electrically conducting fluid" "means that it has sufficient electrical conductivity to achieve the desired effect or purpose . . . " and that "[o]ne of those purposes [is] to provide the pathway between the active electrode or electrodes . . . and the return electrode or electrodes . . . ")]

The Roos article undeniably discloses using electrically conductive fluid "to offer the high-frequency current a path," such that "current flows directly from the cutting loop to the neutral electrode through the adjacent tissue to be cut and the irrigation liquid." [A18728] Current "flows directly from the active cutting electrode, through . . . the irrigation liquid, to the annular neutral electrode" ³ [A18731] Figure 6 (see facing page) illustrates the "operating principle" for the device, [A18728], using current flow lines to show current passing through the liquid, [A18722]. This new current path provides "very good electrical conditions." [A18729] The Roos article thus provides clear disclosure of "fluid that facilitates the passage of electrical current."

The Roos patent similarly claims a space "which is adapted to be filled with liquid to provide electrical conductance." [A18679 (7:59-61)] By describing the

³ Unlike the prior art "forceps" bipolar devices that required tissue contact to work, [A15085 (232:9-18)], the Roos bipolar device was designed specifically to provide a "new current pathway" to facilitate current flow directly through the irrigation liquid, [A18728-29; A18731].

fluid's purpose as "to provide electrical conductance," the patent teaches that the fluid does more than merely permit some limited conduction. One does not describe non-conductive liquid as a liquid "to provide electrical conductance."

[See A26909 (defining "non-conducting"); A26927 (same)]

Faced with clear and convincing disclosure of the electrically conducting fluid, ArthroCare attempts to distract this Court (as it did the jury) by discussing monopolar probes described in the Roos references. ACB at 20-22 & 25-27. Even if the jury could have inferred that the fluid used with some monopolar procedures is not the claimed "electrically conducting fluid," such inferences do not negate the clear disclosure of electrically conducting fluid elsewhere in the references.

ArthroCare also tries to impeach this plain disclosure with a patent that issued almost ten years later. ACB at 22 & 27. This patent's cryptic text does not contradict the Roos references' disclosure of electrically conductive fluid. [See A23661 (1:14-29)] Even if it did, under section 102(b), this later patent legally cannot ameliorate the invalidating effect of the electrically conductive fluid

⁴ Such an inference is not reasonable given the overwhelming contrary evidence. The references themselves do not suggest that the described monopolar probes use non-conductive fluid. The '536 patent inventor acknowledged that some monopolar probes use electrically conducting fluid, [A19783; A15098-100 (286:19-288:20 & 291:19-292:16)], and the jury saw a video of a monopolar probe used with saline, [A15396 (981:3-17)]. U.S Application No. 59,681 (which the '536 patent incorporates by reference) also recognizes that monopolar probes may use electrically conducting fluid. [A19106 (2:3-6) A19122 (19:30-35); A15102 (301:13-302:12); see also A15249 (711:10-712:11); A15319-20 (799:21-800:14 & 803:4-804:10); A15103 (306:3-15)]

disclosed in the Roos references. An invalidating reference does not become less so with the passage of time. Furthermore, if it were acceptable to look to other documents to interpret the Roos references, the most relevant (and contemporaneous) document to consider is the prosecution history of the Roos patent, which reaffirms the disclosure of electrically conducting fluid:

[W]ashing liquid [29] must be allowed to flow out of the endoscope so as to provide the necessary electrical conductor between the [electrodes]....[T]he washing fluid would conduct electrical current just as the tissue fluid and the tissue itself of the human body....[In] the present invention there is always a well-defined current path between the cutting electrode 12 and the neutral electrode 11 through the washing (and tissue) fluid.

[A19339-40 (emphases added); see also A15444-45 (1176:2-1177:8)]

Finally, in arguing that the Roos references lack a fluid supply directing the electrically conducting fluid to the target site, ACB at 24 & 27, ArthroCare continues to ignore this Court's instruction that a reference need not explicitly discuss a feature to anticipate it. See Schering, 339 F.3d at 1379; EMI, 268 F.3d at 1350. Both Roos references disclose the use of electrically conducting fluid directed to the target site, which necessarily requires use of a fluid supply to direct that fluid. [See also A19339 (conductive fluid flows out of the probe)] Indeed, ArthroCare concedes this point by arguing that "the resectoscope includes an optical system and delivers 'irrigation liquid,'" ACB at 31 (emphasis added).

- III. The Court Erred in Dismissing Smith & Nephew's Antitrust Counterclaim
 - A. By Denying Smith & Nephew Due Process, the Court Prevented Smith & Nephew From Curing Any Defect in its Pleading

ArthroCare and Ethicon do not dispute that the court barred Smith & Nephew from responding to the motion to dismiss. They likewise cannot distinguish the cases requiring this Court to vacate the dismissal as a result of this error. See, e.g., Jordan v. County of Montgomery, Pa., 404 F.2d 747, 748 (3d Cir. 1969). Instead, they ask this Court to ignore the law because Smith & Nephew sought reconsideration in the district court. ACB at 66-67; ECB at 14.

Smith & Nephew's motion for reconsideration does not qualify as a meaningful opportunity to be heard. Smith & Nephew's burden on reconsideration was significantly higher than it would have been had the court permitted it to oppose ArthroCare's motion. As the court explained, "motions for reconsideration should be granted sparingly" and "reconsideration is not merely an opportunity to accomplish repetition of arguments that were or should have been presented to the court previously." [A132-33 (internal citation and quotation omitted)] Because the court applied that higher standard in denying the motion for reconsideration, [A133], it did not afford Smith & Nephew a meaningful opportunity to be heard on the motion to dismiss.

B. Rule 9 Does Not Apply to Smith & Nephew's Counterclaim

Ethicon faults Smith & Nephew's counterclaim as lacking the "specificity" supposedly required. ECB at 32. Rule 9 does not apply to Smith & Nephew's pleading, however. Lum v. Bank of Am., 361 F.3d 217, 220 (3d Cir. 2004). The PepsiCo case is inapposite because the Soft Drink Act, see 15 U.S.C. § 3501, does not apply to ArthroCare and Ethicon. Commonwealth of Pa. v. PepsiCo, Inc., 836 F.2d 173, 181 (3d Cir. 1988). Smith & Nephew merely had to put ArthroCare and Ethicon on reasonable notice of its claims. Lum, 361 F.3d at 228. See SNB at 20-21 (quoting portions of counterclaim relating to Section 1 violation).

Even if the counterclaim omitted a necessary factual element, the court first should have directed Smith & Nephew to file an amended counterclaim before entering dismissal. In the Third Circuit, before dismissing a claim, courts should:

expressly state, where appropriate, that the plaintiff has leave to amend within a specified period of time, and that application for dismissal of the action may be made if a timely amendment is not forthcoming within that time.

Borelli v. City of Reading, 532 F.2d 950, 951 n.1 (3d Cir. 1976); see also Shane v. Fauver, 213 F.3d 113, 116 (3d Cir. 2000); District Counsel 47 v. Bradley, 795 F.2d

⁵ ArthroCare and Ethicon impute improper motives to Smith & Nephew's highlighting only the counterclaim sections relevant to the Section 1 violation. ACB at 57 & 60 n.25; ECB at 5. The court's errors in denying due process and ignoring the Section 1 allegations so plainly require this Court to vacate the dismissal that Smith & Nephew need not address its alternative sham litigation allegations on appeal. Smith & Nephew need show only one basis for vacating the dismissal.

310, 316 (3d Cir. 1986). Under Third Circuit law, a court may dismiss a claim only if the litigant refuses to amend the pleading. See, e.g., Borelli, 532 F.2d at 951 n.1.

Here, the court barred Smith & Nephew from responding to ArthroCare's motion and did not permit an amended counterclaim. When Smith & Nephew sought reconsideration, it was impossible to file an amended pleading, as the court already had dismissed the counterclaim and entered judgment. Thus, the court committed reversible error not only by denying Smith & Nephew an opportunity to respond to the motion to dismiss, but also by failing to follow the procedure outlined in <u>Borelli</u>. See <u>District Counsel</u>, 795 F.2d at 316.

As a result of this egregious error and this case's unusual procedural posture, this Court is not obligated to consider only the allegations in the counterclaim, as would be the case if the court had instructed Smith & Nephew to file an amended counterclaim and Smith & Nephew had opted to stand on its original pleading.

Make no mistake, Smith & Nephew urges this Court to vacate the dismissal based solely on the court's failure to allow a response to the motion and to instruct Smith & Nephew to file an amended counterclaim. However, if this Court chooses to

⁶ Typically, a litigant has an opportunity to file an amended complaint when the other side files a motion to dismiss. See Wright & Miller, Fed. Practice and Procedure (1990) § 1480 at 578 ("[I]f the time for serving the responsive pleading is extended by a Rule 12(b) motion, . . . the period for amending as a matter of right also is enlarged."). The Third Circuit augments this right. See, e.g., Borelli, 532 F.3d at 951 n.1.

address the underlying allegations of the Section 1 antitrust violation, it may and should consider all the allegations—including those in Smith & Nephew's briefs—because these allegations would have appeared in an amended counterclaim had the court followed the procedure outlined in <u>Borelli</u>.

C. Under the Facts Alleged, the ArthroCare/Ethicon Agreement Unreasonably Restrains Trade

ArthroCare and Ethicon consume many pages addressing Smith & Nephew's sham litigation allegations. ACB at 57-62; ECB at 17-18. They focus on this unappealed issue to distract attention from their inability to dispute that Noerr-Pennington immunity does not apply to an unlawful settlement agreement. See, e.g., Andrx Pharms., Inc. v. Bioval Corp., Int'l, 256 F.3d 799, 817-18 (D.C. Cir. 2001). Accordingly, ArthroCare and Ethicon's entire opposition rests on their argument that the Agreement is not anti-competitive.

Neither ArthroCare nor Ethicon legitimately disputes that Smith & Nephew pled the first element of a Section 1 violation: an agreement. See Fuentes v. S.

Hills Cardiology, 946 F.2d 196, 198 (3d Cir. 1991) (listing elements). With respect to the elements of restraint of trade and effect on competition, they refuse to accept as true Smith & Nephew's factual allegations and instead argue competing allegations that no court should consider in reviewing a dismissal under Rule 12(b)(6). Steamfitters Local Union No. 420 Welfare Fund v. Philip Morris,

Inc., 171 F.3d 912, 919 (3d Cir. 1999) (A court must accept the complaint's allegations as true.).

For example, ArthroCare argues that Smith & Nephew cannot "show" that the Agreement results in antitrust injury. ACB at 64-65. Smith & Nephew is not required to "show" anything; its allegations are assumed true in the context of a dismissal motion. Additionally, Ethicon asserts that the Agreement had a legitimate purpose. ECB at 29-30.⁷ In this appeal, however, this Court must assume that the Agreement's purpose is "to prevent or restrain other competitors from entering the market." [A311 (¶34)]

1. {

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A settlement agreement that is part of an illegal restraint of trade is anticompetitive. See, e.g., United States v. Singer Mfg. Co., 374 U.S. 174, 189 n.7, 192-94 (1963); Andrx, 256 F.3d at 817-18; In re Buspirone Patent Litig., 185 F. Supp. 2d 363, 366, 378-79 (S.D.N.Y. 2002). Ethicon cites no support for its sweeping statement that settlement "agreements are not anticompetitive and do not have unlawful objectives." ECB at 22.

⁷ Ethicon faults Smith & Nephew for not addressing certain yet unproven "facts" that allegedly show that the Agreement had a legitimate purpose. ECB at 29 n.11. These supposed facts are not germane to whether the court erred in dismissing the counterclaim, and must await a full development of the record.

{

In evaluating the court's dismissal, this Court should not accept these allegations as true—especially when they contradict Smith & Nephew's allegations.

2. The ArthroCare/Ethicon Agreement is Not an Exclusive License

Because ArthroCare did not grant Ethicon an exclusive license, Ethicon's discussion of exclusive licenses is irrelevant. Nevertheless, there is nothing inconsistent between Smith & Nephew's counterclaim and a lawful exclusive license.

Unlike an exclusive license,

Accordingly, the ability of a patentee to enter into a lawful exclusive license does not empower ArthroCare and Ethicon to violate Section 1 by entering into an anticompetitive agreement.

3. Smith & Nephew Sufficiently Alleges Antitrust Injury

The court did not dismiss Smith & Nephew's counterclaim for an alleged failure to plead antitrust injury, even though ArthroCare argued this point in its motion to dismiss. [A27-31] This Court should refrain from addressing the issue of antitrust injury for the first time on appeal. Furthermore, "the existence of an 'antitrust injury' is not typically resolved through a motion to dismiss." Brader v. Allegheny Gen. Hosp., 64 F.3d 869, 876 (3d Cir. 1995). If the Court chooses to address this issue, however, Smith & Nephew adequately alleges injury.

To satisfy the antitrust injury requirement, Smith & Nephew must allege that its injuries stem from either anticompetitive effects of the illegal Agreement or the effects of anticompetitive acts made possible by the Agreement. See Eichorn v. AT&T Corp., 248 F.3d 131, 140 (3d Cir. 2001).

⁸ The Agreement thus belies Ethicon's protests that it is simply an innocent bystander to this litigation.

Thus, ArthroCare and

Ethicon specifically conspired to exclude Smith & Nephew from the market.

ArthroCare and Ethicon claim that Smith & Nephew's injury flows from its exclusion from the market, which is not caused by their unlawful Agreement.

ACB at 62; ECB at 19-21. They offer an alternative cause for Smith & Nephew's injury, and ask this Court to agree with them as a factual matter. However, a court must accept all of Smith & Nephew's allegations as true and draw all inferences in its favor when evaluating a motion to dismiss. Steamfitters, 171 F.3d at 919.

Smith & Nephew is not required to disprove other theories to overturn the court's dismissal.

Eastman Kodak is inapplicable here. In that case, this Court upheld a summary judgment that Eastman did not violate Section 2 of the Sherman Act and Section 7 of the Clayton Act when it enforced a patent it acquired from another.

Eastman Kodak Co. v. Goodyear Tire & Rubber Co., 114 F.3d 1547, 1555-58

(Fed. Cir. 1997), overruled on other grounds by Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1456 (Fed. Cir. 1998) (en banc).

1

Furthermore, unlike the <u>Eastman</u> plaintiff, Smith & Nephew also alleges injuries beyond those stemming from patent enforcement.

Because Smith & Nephew alleges

that the Agreement has injured itself and the competitive market, it adequately alleges antitrust injury. <u>Eichorn</u>, 248 F.3d at 140.

⁹ The jury verdict that the asserted patents are not invalid does not eliminate Smith & Nephew's allegation of injury. The jury did not find these patents "valid." Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1569 (Fed. Cir. 1987) (Patents are not declared "valid."). As demonstrated above (and found by the PTO, [A26892-901]), the '536 patent is invalid.

¹⁰ Ethicon notes that Smith & Nephew has not alleged that ArthroCare offered it less favorable license terms than Ethicon. ECB at 21. Ethicon fails to appreciate that the Agreement requires §

Smith & Nephew's refusal to become a victim of ArthroCare and Ethicon's anticompetitive scheme does not prevent it from seeking redress under the Sherman Act. <u>Cf. Babbitt v. United Farm Workers Nat'l Union</u>, 442 U.S. 289, 298 (1979) ("[O]ne does not have to await the consummation of threatened injury to obtain preventive relief. If the injury is certainly impending, that is enough." (internal quotation omitted)).

D. This Court Should Vacate the Injunction

Ethicon has no support for its statement that courts <u>routinely</u> enter permanent injunctions while defenses are still pending. One decision from 1976, <u>see ACB</u> at 67, is not a routine. Here, Smith & Nephew's counterclaim provides a complete defense to ArthroCare's infringement charges. <u>See SNB</u> at 45. The court factored the dismissal into its decision to enter an injunction. [A123, n.29 ("For this reason [the antitrust counterclaim being dismissed], the court concludes that it is not premature to issue a permanent injunction at this time.")]

ArthroCare misunderstands the burden it must meet to obtain an injunction before the case is finally adjudicated. While this claim remains pending, the injunction should be dissolved unless ArthroCare meets the standard for a preliminary injunction. ArthroCare has not even attempted to do so.

IV. Substantial Evidence Does Not Support Infringement of the '592 Patent Under the Court's Claim Construction

ArthroCare's entire argument to sustain the infringement verdict rests on its misapplication of the court's claim construction. Because ArthroCare cites no evidence of infringement under the properly applied claim construction, this Court should enter judgment of noninfringement of the asserted '592 patent claims and of claim 47 of the '536 patent.

A. ArthroCare Misapplies the Court's Claim Construction

The court construed the "not in contact" and "spaced away" limitations to mean that "the return electrode is not to contact the body at all during the performance of the claimed method." [A15652 (1718:19-25) (emphasis added)]

The claimed method, which involves two "positioning," steps and one "energy application" step, [A465-66 (24:6-21 & 25:43-54)], is performed "when each of the three steps of the claim has been completed." [A15652 (1718:19-25) (emphasis added)] Although there is no time limitation on how long it takes to perform the three steps, [id.], their performance is not simultaneous or instantaneous. For example, the "energy application" step requires current to flow "through the current flow path" established in the second "positioning" step.

[A465-66 (24:6-21 & 25:43-54)] Whether it takes ten seconds or two minutes, there is some time duration required to perform (and complete) all three steps. 11

Instead of challenging the court's construction of these limitations (which ArthroCare lost), ArthroCare invites this Court (as it did the jury) to disregard the construction. [See A15592-93 (1580:17-1582:7 & 1583:20-1584:7)] Inverting the court's construction, which permits infringement only if the return never makes

¹¹ Smith & Nephew has never argued that it avoids infringement "because [it] perform[s] the claimed methods only for short periods of time." See ACB at 13 & 40-42. This case is <u>not</u> about occasional infringement. Smith & Nephew never infringes because the accused devices do not completely perform all three method steps without making tissue contact with the return electrode.

tissue contact "at all" during performance of the method, ArthroCare advocates an interpretation that compels infringement anytime the return <u>ever breaks</u> tissue contact during performance of the method.

B. The Record Contains No Substantial Evidence of Infringement Under a Proper Application of the Claim Construction

The only direct record evidence on use of the accused devices are videos that begin with the devices already partially positioned in the joint. [A19249; A19254; A20067; A22539] The videos do not indicate whether the first or even the second "positioning" steps already have been performed before filming began. As shown in the videos, the return electrode frequently contacts tissue during movement of the probe and during energy application. [A19249; A19254; A20067; A22539; A15407-08 (1025:6-1032:19); A26858-65] ArthroCare's snapshots do not show infringement. Although snapshots can show that the return electrode contacted tissue at some point during performance of the three steps—thereby precluding literal infringement—snapshots cannot prove that the return electrode did not contact tissue at all during performance (and completion) of the three steps. A single freeze-frame instant in time does not represent complete performance of the "positioning" and "energy application" steps. 12

¹² ArthroCare erroneously characterizes the "complete method" as being: "the active electrode is near tissue," "the return electrode is in the fluid," and "energy is applied." ACB at 39 (emphases added). These stationary terms do not reflect the

The circumstantial evidence cited by ArthroCare is insufficient to support the verdict because that evidence also relies on ArthroCare's flawed interpretation of the claim construction. Although Dr. Goldberg may have "testified in detail," ACB at 36, about the supposed infringement, the cited testimony shows he did not apply the proper claim construction: "[A]s long as the return electrode is not in contact while that energy is on, this device infringes." [A15157 (427:6-13) (emphasis added); A15155-56 (422:12-423:6)]; see also ACB at 40 (citing A15397 & A15409) (other witnesses discussing lack of constant contact). Dr. Goldberg testified that a device infringes if it does not maintain constant tissue contact, but, under the court's construction, a device infringes if it does not contact tissue at all during performance of the entire method.

Finally, the product documentation and remaining testimony cited by

ArthroCare pertain to only a partial performance of the method. See SNB at 5456. The Saphyre drawing depicts only a single instant in time—namely, the
"energy application" step, as shown by the illustration of bubbles and current flow
lines. [A22778] Although Dr. Choti testified there are "points in time" during
energy application (i.e., a single step) when the return electrode in the videos did
not contact tissue, he did not state that the return does not contact tissue at all
during the entire duration of the claimed method. [A15257; A15252] Because this

active claim language of "positioning" the active electrode, "positioning" the return electrode, and "applying" energy.

evidence does not relate to a complete performance of the claimed method, it does not support the infringement verdict.

V. The '882 Patent's Certificate of Correction Is Invalid

ArthroCare argues that the Certificate of Correction ("Certificate") is merely a clerical error, ACB at 47-49, but the inquiry does not end there. ArthroCare must show that the Certificate changed claim 1 in a way that was unambiguously required by the intrinsic evidence. Superior, 270 F.3d at 1373. Section 255 allows corrections only if the public would have known there was an error in the original patent and how to correct it. Id. Because self-serving, post-issuance statements in the Request for Certificate of Correction are not part of the original patent's prosecution history, they are not appropriate intrinsic evidence upon which ArthroCare may rely. ArthroCare similarly cannot rely on its prosecuting attorney's or expert's trial testimony because it is not part of the intrinsic evidence. Nor does the examiner's decision to allow the Certificate constitute substantial evidence. The presumption of validity accounts for the examiner's findings. See Am. Hoist, 725 F.2d at 1359.

ArthroCare legitimately cannot dispute that simply changing "the active electrode" to "an active electrode" is not an appropriate way to correct the

antecedent basis problem.¹³ Corrected in this manner, the claim language does not preclude the active electrode from being coupled to the high frequency voltage source, as ArthroCare urges. Although the claim recites that the electrode terminal and the return electrode are coupled to the source, it does not recite that the active electrode is not also coupled thereto. As a result, replacing "the electrode terminal" with "an electrode terminal" does not render claim 1 nonsensical.

Indeed, this change is the only one consistent with the dependent claims. ArthroCare cannot avoid the effect that the Certificate has on claim 53, which strongly indicates that the only correction clearly evident from the intrinsic evidence is to replace "the electrode terminal" with "an electrode terminal." ArthroCare mistakenly argues that claim 53 indirectly depends from claim 28. ACB at 56. Claim 53 depends from claim 52, which depends from claims 23 or 48. [A18633; A18635-37] Claim 23 depends from claim 1. [A18632] Claim 48 does not depend from claim 28. [A18636]. ArthroCare is simply wrong when it states that "claim 53 still would have an antecedent basis issue because claim 28 does not recite 'an active electrode." ACB at 56. Claim 28 is irrelevant to this analysis.

Claim 2, which focuses on the configuration of the electrode terminal (an array), further supports this alternative. [A18631 (24:18-20) (The electrode

¹³ ArthroCare erroneously argues that Smith & Nephew "never once thought to raise this [antecedent basis] argument below," ACB at 51. [See A17130]

terminal "comprises an electrode array including a plurality of isolated electrode terminals.")] As is clear from the figures, the electrode terminal array embodiments include more than two active electrodes. [See A18603-18619 (Figs. 2-15 & 23)] Furthermore, because an array ordinarily consist of more than two elements, [A26912 (defining "array")], claim 2 was not "drafted to claim embodiments with two or more electrode terminals," as ArthroCare asserts. ACB at 56 n.24.

This alternative correction is also completely consistent with the written description and drawings. The patent discloses embodiments having one active electrode (Figs. 21-22 & 24) and embodiments having at least two active electrodes (Figs. 2-15 & 23). [A18604-611; A18629 (20:19-48)] In an embodiment having two active electrodes, the specification refers to them as "electrode terminals 58." [A18627 (16:41-43)] Therefore, the patent naturally uses "active electrode" with "electrode terminal" to signify that the claim corresponds to an embodiment with two or more active electrodes.

ArthroCare's remaining arguments focus on showing that one possible way to correct claim 1 is the way that the Certificate proposes. Because this correction renders claim 53 invalid for a lack of antecedent basis, it is not a viable correction. Even if the Certificate offers one possible way to correct claim 1, ArthroCare fails to identify evidence that this way is the only way supported by the intrinsic

evidence. Because the intrinsic evidence demonstrates at least one other compelling alternative, the Certificate is invalid. See Superior, 270 F.3d at 1373.

VI. ArthroCare Waived its Arguments That This Court Should Remand for a New Trial on the Doctrine of Equivalents

ArthroCare's request for a new trial based on the exclusion of evidence, ACB at 40 n.10, must be rejected. ArthroCare does not argue an alternative ground for affirmance, but instead argues that the exclusion of evidence necessitates "remand" for a new trial on the doctrine of equivalents. Id. Here, the only avenue for attacking the court's exclusion of evidence, which is reviewed for an abuse of discretion, is a cross-appeal. See Odetics, Inc. v. Storage Tech. Corp., 185 F.3d 1259, 1276 (Fed. Cir. 1999); see also Bailey v. Dart Container Corp. of MI, 292 F.3d 1360, 1362 (Fed. Cir. 2002) (cross-appeal necessary when acceptance of argument results in reversal or modification of judgment rather than affirmance).

Because ArthroCare did not move for reconsideration of the dismissal of its cross-appeal within the proscribed fourteen days, it has waived any right to oppose the district court's discretionary ruling. Fed. Cir. R. 45(a) & 40(e). Even if there were no waiver, ArthroCare has not shown that the court abused its discretion in excluding testimony on the doctrine of equivalents based on ArthroCare's failure to include any evidence of equivalents in its case in chief and its expert's failure to opine on this issue in his expert report. [A15433-36 (1131:14-1144:16)]

CONCLUSION

This Court should reverse the dismissal of Smith & Nephew's antitrust counterclaims, reverse the denial of judgment as a matter of law on all accounts, and vacate the permanent injunction.

Dated: December 14, 2004

Respectfully submitted,

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I hereby certify that on December 14, 2004, I caused two copies of the foregoing Non-Confidential Reply Brief For Defendant/Counterclaimant-Appellant, Smith & Nephew, Inc. to be served as follows:

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Counsel for Defendant/Counterclaimant-Appellant, Smith & Nephew, Inc., certifies that the foregoing brief complies with the type-volume limitations of the Federal Rules of Appellate Procedure 32(a)(7)(B).

According to the word count of the word-processing system used to prepare this brief, there are 6977 words in this brief pursuant to the Court's rules of counting.

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